

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-2738-
MAS-RLS**

MDL No. 2738

***THIS DOCUMENT RELATES TO
ALL CASES***

**THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF
LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS OF
DRS. MICHAEL FINAN, CHERYL SAENZ AND KEVIN HOLCOMB**

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The PSC respectfully submits this memorandum in support of its motion to exclude portions of the testimony of the Johnson & Johnson Defendants'¹ (“J&J”) gynecologic oncology experts, Dr. Michael Finan, Dr. Cheryl Saenz, and Dr. Kevin Holcomb, pursuant to Federal Rule of Evidence 104 (a), 702, 703 and 403.

I. INTRODUCTION AND SUMMARY

The general and specific causation opinions of Dr. Finan, Dr. Saenz and Dr. Holcomb are based on speculation, not actual data, and flawed methodology concerning a biologically plausible mechanism.² *First*, as to specific causation, Drs. Saenz, Holcomb, and Finan speculate that imaginary gene mutations, that Plaintiffs do not have and/or are not related to the development of ovarian cancer are to blame for Plaintiffs’ ovarian cancers. These opinions are based on pure speculation and thus, must be excluded.

Second, their opinions concerning biological plausibility are based on flawed methodology because they fail to consider the actual constituents in talcum powder. Although Plaintiffs allege asbestos is in talcum powder, Drs. Saenz, Holcomb, and Finan pretend it does not exist. They deliberately ignore the

¹ The Johnson & Johnson Defendants includes Johnson & Johnson, Johnson & Johnson Consumer Inc., n/k/a/ Johnson & Johnson Consumer Companies, Inc., LTL Management LLC, Johnson & Johnson Holdco (NA), Inc., Kenvue, Inc., and Janssen Pharmaceuticals, Inc.

² *Calhoun v. Yamaha Motor Corp.*, U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (“...the testimony must be reliable....‘the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation...”) (citations omitted). *See also Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003).

evidence, literature and science on asbestos, and at best, cherry pick studies to support their conjecture disguised as legitimate conclusions.

Finally, their opinions on biological plausibility remain based on an incorrect standard, requiring perfected proof of mechanism rather than simply a plausible mechanism as the science and law require.

II. LEGAL STANDARD

The PSC incorporates the legal standard set forth in The Plaintiffs' Steering Committee's Brief Regarding the Rule 702 Standard, and supplements it as set forth herein.

III. OVERVIEW OF J&J'S DESIGNATED GYN ONCOLOGISTS

A gynecologic ("GYN") oncologist is a physician that specializes in the diagnosis and treatment of female reproductive cancers, including cancers of the ovary, uterus, cervix and vulvar, and is responsible for all medical and surgical aspects of the patient's care. GYN oncologists have completed residencies in obstetrics and gynecology, and training through a gynecologic oncology fellowship. As part of patient care, GYN oncologists also evaluate whether a patient is at high risk for gynecologic cancers. In general, a GYN oncologist is qualified to opine on the following issues related to this action: 1) the causes and risk factors of ovarian cancer; 2) the increased risk of ovarian cancer with genital talcum powder use; 3) the migration or transport of particles through the female

reproductive tract; and 4) the molecular mechanism involved in the pathogenesis of ovarian cancer.

J&J designated three GYN oncologists: Dr. Cheryl Saenz, Dr. Kevin Holcomb, and Dr. Michael Finan.³ All three provide the same four general causation opinions: (1) there are known factors that increase or decrease the risk of the development of ovarian cancer;⁴ (2) the epidemiological data does not demonstrate genital talcum powder use is a risk factor for the development of ovarian cancer;⁵ (3) talcum powder cannot migrate from the perineum to the fallopian tubes or ovaries;⁶ and (4) there is no evidence talcum powder causes malignant transformation of epithelial cells.⁷ Drs. Holcomb, Saenz, and Finan do not opine on the individual ingredients in talcum powder, including whether asbestos, fibrous talc, platy talc, heavy metals, or fragrances can cause or increase the risk of ovarian cancer.

All three experts also provide specific causation opinions: Dr. Saenz as to Plaintiffs Converse, Judkins, Newsome, and Rausa; Dr. Holcomb as to Plaintiff

³ J&J previously designated Drs. Saenz and Holcomb to testify on general causation.

⁴ Amended Expert Report of Cheryl C. Saenz, M.D. (May 21, 2024) (“Saenz 2024 Report”) at 5-13, attached hereto as **Exhibit 1**; Expert Report of Kevin Holcomb, MD, FACOG (May 28, 2024) (“Holcomb 2024 Report”) at 5-7, attached hereto as **Exhibit 2**; Expert Report of Michael A. Finan (May 28, 2024) (“Finan Report”) at 7-11, attached hereto as **Exhibit 3**.

⁵ Saenz 2024 Report, Exhibit 1, at 19-41; Holcomb 2024 Report, Exhibit 2, at 7-18; Finan Report, Exhibit 3, 18-41.

⁶ Saenz 2024 Report, Exhibit 1, at 42-44; Holcomb 2024 Report, Exhibit 2, at 19-21; Finan Report, Exhibit 3, at 49-54.

⁷ Saenz 2024 Report, Exhibit 1, at 44-49; Holcomb 2024 Report, Exhibit 2, at 21-23; Finan Report, Exhibit 3, at 54-62.

Gallardo; Dr. Finan as to Plaintiff Bondurant. Because all three conclude that talcum powder does not contribute to ovarian cancer, they do not find that it is a cause of Plaintiffs' ovarian cancers. Instead, Dr. Saenz opines that Ms. Converse's family history of cancer, age, Ashkenazi Jewish heritage, an unsubstantiated history of endometriosis, and use of hormone replacement therapy all increased her risk of developing the disease.⁸ As to Plaintiff Judkins, Dr. Saenz opines there is "no distinct causal mechanism" of her ovarian cancer.⁹ As to Plaintiff Newsome, Dr. Saenz opines that an unsubstantiated history of endometriosis and obesity contributed to Newsome's ovarian cancer, not her talcum powder use.¹⁰

Dr. Holcomb similarly opines that the cause of Ms. Gallardo's ovarian cancer "cannot be specifically identified."¹¹ Nonetheless, he opines that a "hereditary predisposition...is possible in light of her family history" even though testing has not shown the existence of any gene mutation.¹²

⁸ Expert Report of Cheryl C. Saenz, M.D. Case-specific opinions regarding Ms. Hillary Converse (May 28, 2024) ("Saenz Converse Report") at 4-5, 12, attached hereto as **Exhibit 4**.

⁹ Expert Report of Cheryl C. Saenz, M.D. Case-specific opinions regarding Ms. Anne Carter Judkins (May 28, 2024) ("Saenz Judkins Report") at 3, 5, attached hereto as **Exhibit 5**.

¹⁰ Expert Report of Cheryl C. Saenz, M.D. Case-specific opinions regarding Ms. Tamara Newsome (May 28, 2024) ("Saenz Newsome Report") at 3, 6, attached hereto as **Exhibit 6**.

¹¹ Holcomb 2024 Report, Exhibit 2, at 33.

¹² *Id.* at 30, 32.

Dr. Finan opines that Ms. Bondurant's remote history of endometriosis, family history of cancer, and genetic variants "indicat[e] a likely genetic cause of her malignancy."¹³

IV. DRS. SAENZ, HOLCOMB AND FINAN PROVIDE UNSUPPORTED OPINIONS ON IMAGINARY GENETIC MUTATIONS

Drs. Saenz, Holcomb, and Finan all theorize that unknown genetic mutations, which science has not identified as being associated with ovarian cancer, may have caused Plaintiffs' ovarian cancers. These opinions are speculative and must be excluded.

All of the GYN oncologists in this litigation agree that there are known genetic mutations that can increase a woman's risk of getting epithelial ovarian cancer.¹⁴ J&J's GYN oncologists acknowledge that Plaintiffs have none of these known mutations. Yet, they speculate that in the future, new mutations will be identified and associated with ovarian cancer that could be the cause of Plaintiffs' cancers:

- Dr. Saenz: "Even though Ms. Judkins had negative germline testing of 24 genes..., Ms. Judkins may carry a germline mutation that we have yet to identify that contributed to her development of ovarian cancer." (Saenz *Judkins* Report, Exhibit 5, at 3-4).
- Dr. Saenz: "Even though Ms. Newsome had no deleterious mutations identified in germline testing of 25 genes..., there is still a possibility that Ms. Newsome is carrying a germline mutation

¹³ Finan Report, Exhibit 3, at 64, 67.

that science has yet to identify that contributed to her development of ovarian cancer.” (Saenz *Newsome* Report, Exhibit 6, at 3).

- Dr. Saenz: “Even though Ms. Rausa had negative germline testing of 45 genes..., there is still a possibility that Ms. Rausa is carrying a germline mutation that we have yet to identify that contributed to her development of ovarian cancer.” (Saenz *Rausa* Report at 4, attached as **Exhibit 7**).
- Dr. Saenz: “Ms. Converse had negative germline testing of 20 genes...there is still a possibility that Ms. Converse is carrying a germline mutation that has yet to be identified and that contributed to her development of ovarian cancer.” (Saenz *Converse* Report, Exhibit 4, at 4).
- Dr. Finan: Recognizing no documented genetic mutations for Ms. Bondurant but opining, “It should be noted that genetic testing is a dynamic field with new genetic variants found to be associated with ovarian cancer on a regular basis.” (Finan Report at 7, 64; *see also* Finan *Bondurant* Dep. at 76:20-77:3, attached as **Exhibit 8**).
- Dr. Holcomb: While no “deleterious mutations” have been found in Ms. Gallardo’s genetic testing to date, there could be genetic mutations for which Ms. Gallardo has not tested. (Holcomb 2024 Report, Exhibit 2, at 33; Holcomb 06/07/24 Dep. at 342:2-9, 343:13-18 attached as **Exhibit 10**).¹⁵

These opinions rest on multiple layers of speculation. First, additional genes need to be identified as contributing to ovarian cancer. Second, the specific subtype of ovarian cancer associated with the mutation needs to be identified.¹⁶

¹⁴ See 3rd Amended Expert Report of Judith Wolf, MD (2024) at 3, attached hereto as **Exhibit 9**; Holcomb 2024 Report, Exhibit 2, at 5-6.

¹⁵ See also Holcomb 06/07/24 Dep., Exhibit 10, at 344:6-9 (testifying that he could not opine “to a reasonable degree of medical certainty” that there is a hereditary cause of Ms. Gallardo’s cancer).

¹⁶ Holcomb 2024 Report, Exhibit 2, at 6 (“It should be noted that even the hereditary syndromes are associated with distinct histologic types of EOC.”).

Third, Plaintiffs then would have to possess those mutations and the relevant cancer subtype. Suggesting to the jury that this speculative chain of events could happen and thus, is the cause of Plaintiffs' cancers, is improper.

Expert opinions must be based on facts and not "speculation or conjecture." *Fedorczyk v. Caribbean Cruise Lines*, 82 F.3d 69, 75 (3d Cir. 1996). "*Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity." *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 742 (3d Cir. 1994); *see also In re J&J Talcum Powder Prods. Mktg., Sales Practices & Profs. Litig.*, 509 F. supp. 3d 116, 131 (D.N.J. 2020). Thus, an expert opinion "claiming a causal link" must be excluded if it is not based on existing scientific data. *Hoefling v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp. 3d 262, 275 (E.D. Pa. 2021).¹⁷

That this area of science is evolving does not make J&J's GYN oncologists' opinions admissible. Even in matters of "evolving" science, the court must exclude expert opinions that are "too speculative." *Henricksen v. Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1169 (E.D. Wash. 2009); *In re Bausch & Lomb Contacts Lens Solution Prods. Liab. Litig.*, 693 F. Supp. 2d 515, 520 (D.S.C. 2010) ("speculation about future links between MoistureLoc and non-Fusarium infections is not

¹⁷ *Gen. Elec., Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

sufficient”). The Federal Judicial Center explains: “Scientists may delay their decision while they or others gather more data. Judges, on the other hand, must rule on causation based on existing information...[A] judge does not have the option of suspending judgment until more information is available, but must decide after considering the best available science.” Federal Judicial Center, *Reference Manual on Scientific Evidence* (3d ed. 2011), at Preface xiv.

The science and testing to date demonstrate that Plaintiffs have no known genetic mutations that are associated with ovarian cancer. That is all J&J’s GYN oncologists should be permitted to opine on with regard to genetics.

In an effort to concoct support for their unfounded positions, Drs. Saenz and Finan point to the existence in genetic “variants of unknown significance” (VUS), suggesting that the VUSs may actually be yet-to-be-identified genetic mutations that caused Plaintiffs’ cancers.¹⁸

The National Cancer Institute defines a VUS as “[a] change in a gene’s DNA sequence that has an unknown significance on a person’s health.”¹⁹ It is not known whether a VUS has any effect on cancer, let alone the type of ovarian

¹⁸ Saenz *Judkins* Report at 3 (“a variant of unknown significance in the PTEN gene”); Saenz *Newsome* Report at 3 (“a variant of uncertain significance in the MUTYH gene”); Saenz *Rausa* Report at 4 (“a variant of uncertain significance in the FH gene”); Saenz *Converse* Report at 4 (“two variants of uncertain significance”); Finan Report at 64 (“variant of unknown significance (VUS) in the PTCH1 gene”).

¹⁹ National Cancer Institution, NCI Dictionaries (available at <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/variant-of-uncertain-significance>)

cancer Plaintiffs each have. In fact, Dr. Finan admits that some VUSs have been found to be “insignificant” and even protective against cancer. *See Finan Carl Dep.* at 112:5-10, attached hereto as **Exhibit 11**. Dr. Saenz and Dr. Finan both agree that based on the literature, there is no current association between the variants Plaintiffs have and ovarian cancer. *See Finan Bondurant Dep.*, Exhibit 8, at 77:20-78:1; Saenz 06/19/24 Dep. at 103:7-14, attached hereto as **Exhibit 12**; Saenz 06/20/24 Dep. at 478:1-7, attached hereto as **Exhibit 13**. Suggesting to the jury that genetic variants that have not been associated with ovarian cancer could be the cause of Plaintiffs’ cancers is speculative and improper.²⁰

Additionally, these opinions mislead the jury into believing association of Plaintiffs’ ovarian cancers to an inherited genetic mutation is inevitable.²¹ J&J’s GYN oncologists admit that most ovarian cancers are not associated with a genetic mutation. Dr. Holcomb testified that only 15-20% of ovarian cancers are believed to be associated with an inherited genetic mutation.²² However, he concedes that the majority of these cases are associated with mutations of the BRCA1 and 2

²⁰ See **Exhibit 14** (*Valadez v. Johnson & Johnson et al.*, Case No. 22CV012759 (May 4, 2023 Order)) (holding that compelling genetic testing is only appropriate “as to specific germline (inherited) genetic mutations where the moving defendant has presented evidence in the form of peer-reviewed medical literature to support a finding that a specific germline genetic mutation can be cause of mesothelioma independent of any alleged asbestos exposure”).

²¹ Inherited genetic mutations on which Drs. Saenz, Holcomb, and Finan opine, are something a person is born with. This is different than somatic or “acquired” mutations, which occur after birth, and result from events or exposures that cause the gene mutation. *See Second Amended Rule 26 Expert Report of Shawn Levy, PhD*, at 6, attached hereto as **Exhibit 15**.

²² Holcomb 2024 Dep., Exhibit 10, at 344:15-17 (“15-20% of ovarian cancers are thought to be due to genetic predisposition syndromes now”).

genes and Lynch syndrome, with up to 70% related to BRCA1 and 2.²³ Plaintiffs do not have these genetic mutations.²⁴

Additionally, not everyone with an inherited genetic mutation gets cancer. As Dr. Saenz states, “[t]he lifetime risk of developing ovarian cancer for a woman who inherited a deleterious mutation varies, as it is dependent upon the individual mutation...” *See* Saenz 2024 Report, Exhibit 1, at 6. This means the vast majority of ovarian cancer diagnoses have no association with inherited genetic mutations and those that do, are related to mutations Plaintiffs are confirmed to not have. To suggest to the jury that an inherited genetic mutation is likely to be identified in the future as the cause of Plaintiffs’ cancers is misleading, speculative, and not based on the scientific data.

Accordingly, the Court should exclude the speculative opinions of Drs. Saenz, Holcomb and Finan that suggest Plaintiffs’ cancers are the result of imaginary, yet-to-be-identified genetic mutations.

V. DR. SAENZ, DR. HOLCOMB, AND DR. FINAN OPINIONS ON BIOLOGICAL PLAUSIBILITY ARE BASED ON FLAWED METHODOLOGY

²³ *See* Holcomb 2024 Dep., Exhibit 10, at 344:24-345:3, 345:16-20; 3rd Amended Expert Report of Daniel Clarke-Pearson, MD (2024) at 6 (evidence that up to 75% of hereditary ovarian cancers associated with BRCA1 and BRCA2 mutations), attached hereto as **Exhibit 16**; Wolf 2024 Report, Exhibit 9, at 3 (same).

²⁴ *See* Saenz *Newsome* Report, Exhibit 6, at 2; Saenz *Judkins* Report, Exhibit 5, at 2; Saenz *Converse* Report, Exhibit 4, at 2-3; Saenz *Rausa* Report, Exhibit 7, at 3; Finan Report, Exhibit 3, at 64:22-65:10.

A. J&J's GYN Oncologists Fail to Provide Opinions on the Known Constituents of Talcum Powder

Plaintiffs contend that J&J's talcum powder contains asbestos. In October 2019, the FDA found asbestos in a sample of J&J's Baby Powder, resulting in J&J recalling 33,000 bottles of the product.²⁵ Plaintiffs experts also testify to the presence of asbestos in Baby Powder and its relationship to ovarian cancer.²⁶ J&J's GYN oncologists acknowledge Plaintiffs' assertion that talcum powder contains asbestos.²⁷ Yet they ignore asbestos when opining on biological plausibility, focusing only on mechanistic studies concerning talc and failing to consider the studies that demonstrate that talc with asbestos is known to be genotoxic.²⁸

As the Court previously recognized, biological plausibility asks “whether the hypothesized causal link is credible in light of what is known from science and medicine about the human body and the potentially offending agent.” *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Litig.*, 509 F. Supp. 3d 116, 174 (D.N.J. 2020) (quoting *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 25 (1st Cir. 2011)). Drs. Saenz, Holcomb and Finan ignore the “offending agent,” which is talcum powder – a substance consisting of

²⁵ Dyer, Owen. Johnson & Johnson Recalls its Baby Powder after FDA Finds Asbestos in Sample. BMJ (2019), attached hereto as **Exhibit 17**.

²⁶ See Longo & Rigler 2nd Supp. Report (February 1, 2019), attached hereto as **Exhibit 18**; Longo 3rd Supp. Report (November 17, 2023), attached hereto as **Exhibit 19**; see also Wolf 2024 Report, Exhibit 9, at 12.

²⁷ See Saenz 2024 Report, Exhibit 1, at 54; Holcomb 2024 Report, Exhibit 2, at 6-7.

²⁸ See International Agency for Research on Cancer (IARC), Volume 100C, *Arsenic, Metals, Fibres and Dusts*, at 288-291 (2012), attached hereto as **Exhibit 20**.

talc (both platy and fibrous), asbestos, and other constituents. They opine that it is not biologically plausible for talcum powder to contribute to ovarian cancer because *talc* does not migrate from the perineum to the ovaries and *talc* does not cause malignant transformation.

Dr. Holcomb has not reviewed any literature on asbestos and ovarian cancer since 2019, has not seen any of J&J's internal documents showing asbestos in talcum powder, and is unaware of the FDA's findings of asbestos in J&J's Baby Powder. *See* Holcomb 06/07/24 Dep., Exhibit 10, at 38:24-39:8, 165:7-10, 166:7-11, 174:21-175:7, 189:11-16. Concerning migration, Dr. Holcomb limits his opinion to talc and concedes he does not "remember reading any literature on asbestos transport." *Id.* at 129:9-22. He has not looked at the literature that shows asbestos in the tissue of ovaries. *Id.* 130:4-7. As a result, he has no opinion on whether asbestos fibers or particles can reach the ovaries. *Id.* at 130:17-21.

As to whether talcum powder that gets to the ovary can cause ovarian cancer, Dr. Holcomb again focuses solely on talc. He does not even know whether asbestos is genotoxic. *Id.* at 131:23-24 ("Q: Is asbestos genotoxic? A: Actually, I don't know."). He also acknowledged that whether there is any safe level of asbestos exposure is "outside my expertise." *Id.* 188:6-14. Nonetheless, Dr. Holcomb does not advise his patients that it is safe to put asbestos on their genitals. *See* Holcomb 03/27/19 Dep. at 239:7-9, attached hereto as **Exhibit 21**.

Dr. Saenz has not seen any testing results or data about the presence of asbestos in J&J's Baby Powder. *See* Saenz 06/19/24 Dep., Exhibit 12, at 279:16-21; Saenz 06/20/24 Dep., Exhibit 13, at 428:3-5. She also did not do a literature review regarding ovarian cancer and exposure to asbestos. *See* Saenz 06/19/24 Dep., Exhibit 12, at 284:1-6. Nor did she study the "mechanism of carcinogenesis of asbestos" and ovarian cancer. *See* Saenz 06/20/24 Dep., Exhibit 13, at 340:10-12. As a result, her opinions on whether asbestos causes ovarian cancer are limited to a handful of cherry-picked studies. *See* Saenz 2024 Report, Exhibit 1, at 57-58. On migration, while Dr. Saenz admits that asbestos has been found in ovary tissue, she concludes, without citation, that "[t]he path of migration has not been established...." *Id.* at 58.

Dr. Finan goes further, concluding that asbestos does not cause ovarian cancer, while admitting he has not studied asbestos and its role to cancer, does not know the mechanism by which asbestos causes any cancer, and admits he knows "[v]ery little" about asbestos. *See* Finan *Carl* Dep., Exhibit 11, at 221:19-222:19. He does not know which types of asbestos are carcinogenic or what conditions have been linked to asbestos. *Id.* at 223:14-19. He also has not reviewed any literature on the migration of asbestos fibers through the vagina, and does not know whether they can be absorbed into the bloodstream. *Id.* at 66:21-67:13, 221:19-222:19. While Dr. Finan admits that "asbestos is a known carcinogen to the

...lungs and peritoneum,” he has “no idea” how asbestos gets to the peritoneum. *Id.* at 134:2-11. Dr. Finan also has not reviewed any documents concerning the presence of asbestos in J&J’s Baby Powder or whether it causes ovarian cancer. *Id.* at 223:1-8.

J&J’s GYN oncologists ignore asbestos because it “is one of the most potent carcinogens known,” with all forms being carcinogenic. *See* Wolf 2024 Report, Exhibit 9, at 12; Clarke-Pearson 2024 Report, Exhibit 16, at 7. IARC concluded that asbestos and talc containing asbestiform fibers cause ovarian cancer and “consumer products (e.g., cosmetics, pharmaceuticals) are the primary source of exposure to talc for the general population. Inhalation and dermal contact (i.e., through perineal application of talcum powders) are the primary routes of exposure.” *See* IARC 2012, Exhibit 20, at 232.

By ignoring asbestos and focusing solely on talc, one component of talcum powder, J&J’s GYN oncologists are engaging in impermissible cherry-picking. The cherry-picking of data and facts “does not reflect scientific knowledge, is not derived by scientific method and is not ‘good science.’”²⁹ “[A]ny theory that fails

²⁹ *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 524 F. Supp. 2d at 1176; *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 796–800 (3d Cir. 2017) (“An expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead ‘selectively chooses his support from the scientific landscape.’”); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 676 (S.D.W. Va. 2014) “[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.”) *Poosh v. Phillip Morris USA, Inc.*, 287 F.R.D. 543, 546 (N.D. Cal. 2012) (“A methodology may not be

to explain information that otherwise would tend to cast doubt on that theory is inherently suspect,” and “courts have excluded expert testimony” “where the expert selectively chose his support from the scientific landscape”³⁰ as Dr. Saenz, Dr. Holcomb, and Dr. Finan have done here with regard to biological plausibility. It “is hardly scientific.”³¹ It is “inherently unreliable.”³²

The method used by Drs. Saenz, Holcomb, and Finan to arrive at opinions on biological plausibility is flawed and scientifically unreliable. These experts do not conduct a scientific review of the literature concerning asbestos and thus, ignored scientific studies concerning the offending agent, which do not support their opinions. The Third Circuit has deemed expert opinions unreliable in situations like this, where the experts ignored facts when formulating their opinions.³³ Thus, their opinions on biological plausibility should be excluded.

reliable if an expert fails to address and exclude alternative explanations for the data on which he bases his findings or rejects studies reporting contrary empirical findings.”); *Abarca v. Franklin Cty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) (“A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted.” (internal citations omitted)).

³⁰ *In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005).

³¹ *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596 (9th Cir. 1996).

³² *In re Bausch & Lomb, Inc. Contact Lens Solution Prods. Liab. Litig.*, 2009 WL 2760462, at *14 (D.S.C. Aug. 26, 2009).

³³ *See Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d 2000); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002), *aff'd*, 68 F. App'x 356 (3d Cir. 2003) (“in order for an expert's opinions based on evidence to be reliable and admissible, “all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.”)

B. J&J's GYN Oncologists Apply the Wrong Standard to Biological Plausibility

The PSC previously moved to exclude Dr. Saenz's and Dr. Holcomb's biological plausibility opinions as being based on an incorrect standard requiring perfected "proof" of migration, inflammation, and malignant transformation, rather than a plausible mechanism.³⁴ The Court rejected this argument based on Dr. Saenz's testimony at the *Daubert* hearing, conceding the correct standard.³⁵ However, in their recent expert reports, J&J's GYN oncologists, including Dr. Saenz, revert back to the incorrect "proof" standard.

Previously, Dr. Saenz opined that there must be "scientific proof" of mechanism – i.e., "some proof that a particulate matter applied to the perineum can actually make it to the ovaries for the hypothesis that talc can cause ovarian cancer to be so." *See* Saenz 03/13/19 Dep. at 197:14-198:2, 246:4-11 ("scientific proof"), attached as **Exhibit 22**). Because she had not seen a precise study on migration of talcum powder and its constituents from the perineum to the ovaries or resulting inflammation in the ovaries, Dr. Saenz concluded that it was not biologically plausible for talcum powder to cause ovarian cancer. *Id.* at 208:16-25; *id.* at 218:20-219:1; *see also* Saenz 2019 Report at 8, attached as **Exhibit 23** ("There is not a single study demonstrating such migration from the perineum to the

³⁴ *In re J&J Talcum Powder*, 509 F. Supp. 3d at 174-75.

³⁵ *Id.* at 195.

ovaries.”); *Id.* at 20 (“There is no literature that particulate matter such as talcum powder, applied to the perineum, can migrate to the ovaries.”).

Then, at the *Daubert* hearing, Dr. Saenz conceded “that biological plausibility does not require ‘proof positive, nor does it need to be an exact representation of whatever is your hypothesis....’”³⁶

However, in her updated report, Dr. Saenz once again confirms that she continues to believe that biological plausibility needs a precise study that shows migration of talc to the ovaries resulting in inflammation and malignant transformation. Saenz 2024 Report, Exhibit 1, at 17-18 (“[T]here is not a single study demonstrating such migration from the external perineum up through the reproductive tract to the ovaries... Nor is there a single publication that identifies inflammation anywhere in a woman’s reproductive tract resulting from external talc application to the perineal area.”); Saenz 06/19/24 Dep., Exhibit 12, at 285:23-286:1 (there’s “no data for migration from the perineum, and there’s no biologic gradient data”); Saenz 06/20/24 Dep., Exhibit 13, at 325:14-17 (“There’s no biological plausibility...There’s no data for the migration of talc from the perineum.”).

Drs. Holcomb and Finan apply the same incorrect standard. Dr. Holcomb expects to be “convinced” of the mechanism to have biological plausibility.

³⁶ *In re J&J Talcum Powder*, 509 F. Supp. 3d at 195 (quoting Saenz).

Holcomb 06/07/24 Dep., Exhibit 10, at 131:14-22, 392:22-393:4. He concedes there are studies that show talc can migrate to the ovaries. *Id.* at 108:10-15. However, because he has not seen a study that shows talc dusted on the perineum can migrate, he is “not convinced” it can occur. *Id.* at 108:15-19. Similarly, while he concedes that chronic inflammation causes cancer, Dr. Holcomb does not know whether it causes ovarian cancer because he says it has not yet been “proven” in the literature. *Id.* at 421:15-423:12. Still, he did not conduct a literature review of chronic inflammation and ovarian cancer as part of his opinions in this case. *Id.* at 423:15-20.

On inflammation, Dr. Finan goes one step further, conceding that inflammation can cause cancer, but adamantly concluding that ovarian cancer is not caused by inflammation, although he concedes he does not know what causes non-heredity cases. *See* Finan Report, Exhibit 3, at 5, 54; Finan *Carl* Dep., Exhibit 11, at 169:12-170:8. Dr. Finan again bases his conclusions on the absence of precise studies: “My opinion is that there are no studies that demonstrate that talcum powder applied as a dusting to the female perineum can migrate upwards through the female genital tract and reach the fallopian tubes or ovaries. That’s my opinion.” *See* Finan *Carl* Dep., Exhibit 11, at 68:8-13; *see also* Finan Report, Exhibit 3, at 4. Similarly, with regard to inflammation as a plausible mechanism he opines: “There are no studies showing that sprinkling talcum powder on benign

ovarian cells in cell culture causes them to transform into malignant cells. Nor are there any studies that demonstrate...malignant transformation.” See Finan Carl Dep., Exhibit 11, at 60.

All three experts apply the wrong standard for biological plausibility. Plaintiffs are not required to point to a precise study to demonstrate biological plausibility. The *Reference Manual on Scientific Evidence* describes biological plausibility as a judgment based on existing knowledge as to whether an agent plausibly could cause an adverse outcome. See Michael D. Green, *et al.*, *Reference Manual on Scientific Evidence*, at 604-05 (3d Ed. 2011), attached hereto as **Exhibit 24**. Biologic plausibility lends credence to an inference of causation. *Id.*

Plaintiffs do not have the burden to prove the precise mechanism by which migration and ovarian carcinogenesis occur.³⁷ To require that a mechanism be

³⁷ See *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 181 (S.D.N.Y. 2009) (“[b]iologic plausibility is a judgment about whether an agent plausibly could cause a disease, based on existing knowledge about human biology and disease pathology” ... “That the mechanism remains unknown does not mean that the one proposed by the PSC’s experts is not widely accepted as plausible.”); see also *In re Neurontin Mktg., Sales Practices, & Prod. Liab. Litig.*, 612 F. Supp. 2d 116, 149 (D. Mass. 2009) (causation was supported by biologic plausibility notwithstanding the “robust debate in the scientific community” regarding the proposed mechanism); *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1247 (W.D. Wash. 2003) (“The fact that the mechanism remains unclear does not call the reliability of the opinion into question.”); *In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 2007-MD-1871, 2011 WL 13576, at *4 (E.D. Pa. Jan. 4, 2011); *Rowland v. Novartis Pharm. Corp.*, 149 F.Supp.3d 553, *17 (2014) (defining biological plausibility as a reasonable association between exposure and disease based on what is known about the disease); *In re Fosamax Prods. Liab. Litig.*, 2013 WL 155869, *3 (D.N.J. April 10, 2013) (defining biological plausibility as “coherence with existing knowledge”); *Bartoli v. Novartis Pharm. Corp.*, No. CIV.A. 3:13-0724, 2014 WL 1515870, at *7 (M.D. Pa. Apr. 17, 2014) (citing *In re Pfizer Inc. Sec. Litig.*, No. 04CIV.9866(LTS)(JLC), 2010 WL 1047618, at *6 (S.D.N.Y. Mar. 22, 2010)

proven is the incorrect standard.³⁸

In fact, when applying the correct “plausibility” standard, Dr. Saenz and Dr. Holcomb agree with Plaintiffs that the literature demonstrates a biologically plausible mechanism. Dr. Saenz conceded that “in terms of biologic plausibility, there is some data that there can be particulate matter that can make it to the ovaries” once it gets into the vagina. *See* Saenz 2019 Dep., Exhibit 22, at 209:7-14; *id.* at 217:4-5 (“There is a way that you can pass up through the cervix once something is in the vagina.”); *id.* at 196:5-22 (recognizing that study conclusions regarding migration “are described as plausibility”).

Similarly, when asked whether it was his opinion “that there is no biologically plausible mechanism by which talc powder products can translocate or migrate from the perineum to the fallopian tubes and ovaries,” Dr. Holcomb

(allowing testimony regarding biological plausibility “[w]here a ‘hypothesis has been deemed plausible and credible in the relevant medical literature’ and where it is within an expert’s field of expertise based on training, experience, and history of publication.”); *Wicker v. Consol. Rail Corp.*, 371 F. Supp. 2d 702 (W.D. Pa. 2005) (defining biological plausibility as “coherence with existing knowledge”); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 593 (D.N.J. 2002) (defining biological plausibility as the existence of a biologically plausible mechanism that could cause the adverse outcome of interest); *In re Trasyolol Prod. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489730, at *7–*8 (S.D. Fla. Mar. 19, 2010) (plausible biological mechanism need not be “proven” just “reliable,” and using terms of “can” and “may” in regards to such does not render opinion unreliable); *In re Chantix (Varenicline) Prod. Liab. Litig.*, 889 F. Supp. 2d 1272, 1300 (N.D. Ala. 2012) (mechanism theory deemed reliable despite “debate in the scientific community as to whether Dr. Bechara’s dopamine depletion theory for Chantix can explain major depression and other neuropsychiatric injuries. . . .debate is not a basis for exclusion”); *In re Hanford Nuclear Reservation Litig.*, No. CY-91-3015-AAM, 1998 WL 775340, at *7 (E.D. Wash. Aug. 21, 1998) (“ ‘biological plausibility’ is not the same as ‘biological certainty.’ . . . [s]uch certainty cannot be attained.”).

³⁸ *In re Trasyolol Products Liability Litigation*, 2010 WL 1489730, at *7–*8.

explained: “[T]here is no expelling evidence that I’ve seen that has the ability do it. So I’m not ask – I’m not sure if you’re asking is it just possible or is it – is any evidence to suggest that it can happen. Because if – if you’re saying is it possible, I’d have to say yes.” *See* Holcomb 03/27/19 Dep., Exhibit 21, at 421:23-422:15. Drs. Saenz’s, Holcomb’s, and Finan’s contrary opinions regarding biological plausibility based on an improper standard of proof should be excluded.

The heightened standard that J&J’s GYN oncologists apply is not compatible with the civil law preponderance of evidence standard or with the definition of general causation. Longstanding legal principles govern the standard of proof in a civil case. In the Third Circuit and elsewhere, a plaintiff must prove the elements of the claims by a preponderance of evidence. This holds true for evidence of causation, including expert testimony. Plaintiffs only are required to prove causation is “more probable than not.”³⁹ “It would be unreasonable to conclude that the subject of scientific testimony must be ‘known’ to a certainty; arguably, there are no certainties in science.”⁴⁰

As the U.S. Supreme Court has recognized, outside the courtroom, it is a fallacy that scientists insist on certainty or near certainty in making judgments. “[M]edical professionals and researchers do not limit the data they consider to the

³⁹ *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 780 (3d Cir. 1994).

⁴⁰ *Daubert*, 509 U.S. at 590. *See also Horan v. Dilbet, Inc.*, 2015 WL 5054856, *13 (D.N.J. Aug. 26, 2015) (noting the unreasonableness of subjecting scientific testimony to a certainty standard).

results of randomized clinical trials or to statistically significant evidence.”⁴¹ The Third Circuit is clear that “it would be unreasonable to conclude that the subject of scientific testimony must be ‘known’ to a ‘certainty.’”⁴²

Nor will such testimony “assist the trier of fact.” To the contrary, it will tend to obfuscate and confuse. Opinions that are based on the incorrect legal standard cannot be helpful to the jury and, in fact, create confusion. The very purpose of expert testimony is to help the jury understand the evidence or determine a fact in issue.⁴³ In its gate-keeper role, the court is tasked with balancing the admission of reliable, helpful expert testimony with the exclusion of that which is misleading or confusing.⁴⁴

Expert witness testimony couched in the phrases like “I’m not convinced” and there is no “documented scientific proof” is powerful and resonant. *See* Holcomb 06/07/24 Dep., Exhibit 10, at 108:18; Saenz 2019 Dep., Exhibit 22, at 196:21-22. And when uttered from the mouths of experts, this testimony poses a strong risk of misleading the jury to give it undue weight.⁴⁵

⁴¹ *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 40-42 (2011)

⁴² *Horan v. Dilbet, Inc.*, 2015 WL 5054856, *13 (D.N.J. Aug. 26, 2015) (*citing Daubert*, 509 U.S. at 590).

⁴³ Fed. Rule Evid. 702 (a).

⁴⁴ *See Daubert*, 509 U.S. at 595; *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 746 (3d Cir. 1994) (“[A]dmissibility of scientific testimony turns not only on reliability but also the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury...in conducting this balancing inquiry, there is a presumption of helpfulness.”).

⁴⁵ *See Nye v. Mistick*, 2015 WL 11511580, *5, n.3 (M.D. Pa. Feb. 24, 2015) (cautioning that experts that exude improper authority can lead juries to give their opinions more weight).

The “certainty” testimony is sure to confuse the jury during deliberation because it contradicts the jury instruction that plaintiffs must prove their claims by a preponderance of the evidence. *See Smith v. Ryan*, 813 F.3d 1175, 1199 (9th Cir. 2016) (“If a trained psychiatrist has difficulty with the categorical ‘beyond a reasonable doubt’ standard, the untrained lay juror—or indeed even a trained judge—who is required to rely upon expert opinion could be forced by the criminal law standard of proof to reject commitment for many patients desperately in need of institutionalized psychiatric care.”). Drs. Saenz’s, Holcomb’s, and Finan’s opinions amount to nothing more than an incorrect personal, subjective standard for weighing evidence and should not be permitted.

Drs. Saenz, Holcomb, and Finan cannot provide coherent opinions on biological mechanism based on an incorrect standard. Their opinions should be excluded.

VI. CONCLUSION

For this and the other foregoing reasons, the Court should grant the PSC’s motion *in limine* to exclude the opinions of Dr. Cheryl Saenz, Dr. Kevin Holcomb, and Dr. Michael Finan from this proceeding concerning (1) potential genetic mutations as the cause of Plaintiffs’ cancer and (2) biological plausibility.

Respectfully submitted,

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